



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,872	09/30/2003	Galina Fomovskaia	56075-PCT-CIP-C (45858)	7999
21874 7590 04/27/2007 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER WILDER, CYNTHIA B	
			ART UNIT	PAPER NUMBER
			1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.		Applicant(s)	
	10/676,872		FOMOVSKAIA ET AL.	
	Examiner		Art Unit	
	Cynthia B. Wilder, Ph.D.		1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-8, 12-14, 16 and 37-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-8, 12-14, 16, and 37-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed 1/22/2007 is acknowledged and has been entered. Claims 4-8, 12 and 16 have been amended. Claims 1-3, 9-11, 15, and 17-36 have been canceled. Claims 37-52 have been added. Claims 4-8, 12-14, 16, and 37-52 are pending. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons that follow. The new grounds of rejections presented in this Office action are necessitated by Applicant's amendment of the claims. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

This action is made FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Rejection

3. The claim rejection under 35 USC 112 second paragraph directed to claim 5 is withdrawn in view of Applicant's amendment. The prior art rejection under 35 USC 102(b) directed to claims 4-8 and 12-17 as being anticipated by Bloch et al is maintained and discussed. The claim rejection under 35 USC 102(b) directed to claims 4-8 and 12-17 is withdrawn in view of Applicant's amendment.

Claim Rejections - 35 USC § 102(b)

Art Unit: 1637

4. Once again, claims 4-8 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Bloch et al., {Bloch, herein} (US 4,789,630, December 1988). Regarding claims 4 and 5, Bloch teaches a solid matrix, wherein the solid matrix comprises nitrocellulose or nylon (col. 17, lines 63-64); a coating functionally associated with the solid matrix, wherein the coating comprises an anionic surfactant or detergent capable of cellular lysis (col. 14, lines 8-14 and 56-64); and an indicator for indicating the presence of nucleic acid, which is maintained on the solid support, wherein said indicator is a color indicator or fluorescent indicator (col. 31, lines 9-18; see also, col. 23, lines 39-47 and col. 11, lines 28-30). Bloch et al also teaches the components in the form of a kit (col. 23, lines 18-67).

Regarding claim 6, Bloch teaches the substrate of claim 4, wherein the substrate is in a shape from the group consisting essentially of a sheet or ball (col. 8, lines 9-10; col. 12, lines 21-22 and col. 17, lines 54-58).

Regarding claim 7, Bloch teaches the substrate of claim 6, wherein said substrate further includes an integrity maintenance means (col. 35, line 68 to col. 36, line 1).

Regarding claim 8, Bloch teaches the substrate of claim 7, wherein said substrate is a sheet (membrane), said integrity maintenance means is a plastic bag (see col. 35, line 68 to col. 36, line 1).

Regarding claim 12, Bloch teaches a kit comprising a dry substrate consisting: a solid matrix, wherein the solid matrix comprises nitrocellulose or nylon (col. 17, lines 63-64); a coating, wherein the coating comprises an anionic surfactant or detergent

Art Unit: 1637

capable of cellular lysis (col. 14, lines 8-14 and 56-64); and an indicator for indicating the presence of nucleic acid, which is maintained on the solid support, wherein said indicator is a color indicator or fluorescent indicator (col. 31, lines 9-18; see also, col. 23, lines 39-47 and col. 11, lines 28-30) and integrity maintenance means (col. 35, line 68 to col. 36, line 1).

Regarding claim 13, Bloch teaches the kit of claim 12, wherein the coated matrix is in a shape from the group consisting essentially of a sheet or ball or dipstick (swab) (col. 8, lines 9-10; col. 12, lines 21-22 and col. 17, lines 54-58).

Regarding claim 14, Bloch teaches the kit of claim 12, wherein said coated matrix is in a shape selected from the group consisting essentially of a plastic bag (col. 35, line 68 to col. 36, line 1) or cellophane and parafilm (col. 8, lines 9-10; col. 12, lines 21-22 and col. 17, lines 54-58).

Applicant's Traversal

5. Applicant traverses the rejection on the following ground: Applicant summarizes the Examiner's rejection and states that Applicant's respectfully disagree even without the present amendments. Applicant recites the claims as amended. Applicant states that Patent office seems to be equating Southern blotting, dot blotting and similar techniques with the dry solid medium for the claims, but in the present invention and chemical coating is already sorbed to the matrix to result in a dry solid medium, while Southern blotting and similar techniques apply purified DNA in an anion surfactant solution to a solid membrane surface for the detection of specific areas of the DNA.

Art Unit: 1637

Applicant states that here, claims 4, 12 and 16 and the claims dependent thereon, are directed to a dry substrate, the dry substrate comprising a solid matrix and a coating functionally associated with the solid matrix which facilitates cellular lysis. Applicant states that cells, blood, or other biological sample are brought into contact with the dry substrate, which itself facilitates cellular lysis. Applicant states that the nucleic acid is maintained on the solid matrix, where it is detected. Applicant moreover, the anionic surfactants of Bloch are directed toward facilitating use of the dry ion, rather than lysing the cells, and to the detection of DNA, for example, as part of a dot blot of previously isolated DNA or a blot of cells which are subsequently lysed by wetting with a separate lysis buffer, or after the DNA has been run on gel. Applicant states that finally, the integrity means described by Bloch is intended to keep the membrane wet and prevent it from drying out. Applicant states that in contrast, the integrity maintenances means of the present invention has the exact opposite purpose - namely, to keep the membrane dry to stop bacterial or fungal growth. Applicant states that while the specification mention one embodiment having an airtight seal, it is clear that concern here is with prevention of bacterial contamination. Applicant states that exposure to air can bring moisture with it. Applicant respectfully requests the Examiner's reconsideration of these claims accordingly.

Examiner's Response

6. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons that follow: In response to Applicant's arguments, it is

Art Unit: 1637

noted that the courts have established that during patent examination the pending claims must be interpreted as broadly as their terms reasonably allow (*In re Zletz*, 893 F.2d 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989)). In this case, the claims are broadly drawn to a kit comprising reagents, not a method. A kit does not impart functionality but rather only provides a compilation of materials. Such limitations as "for indicating the presence of nucleic acid in a sample" as recited in the claims is an intended use limitation of the claimed nucleic acid library that is not afforded any patentable weight because the limitation does not result in a structural difference between the claimed invention and the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

In response to Applicant's arguments that the limitation "coating functionally associated with the solid matrix which facilitates cellular lysis" distinguishes the instant invention over the prior art of Bloch, it is noted that the limitation "functionally associated" is broadly defined in the instant invention as meaning that the "coating is disposed, sorbed or otherwise associated with the support. The specification states that "that is, the coating can be adsorbed, absorbed, coated over, or otherwise disposed in functional relationship with the support". The specification additionally provides an example wherein the support is a filter membrane and the coating is a binder such as polyvinylacrylamide, polyvinylacrylate, polyvinylalcohol and gelatin. The prior art of Bloch et al meet the limitations of the term "coating functionally associated with the support" as broadly defined in the instant application because Bloch et al teach wherein

Art Unit: 1637

support comprising a polymeric anionic particles (col. 17, lines 52-68 to col. 18, lines 1-2). Bloch further defines wherein the anionic particle may include "polyacrylate, polymethacrylate, dextran, sulfate, sulfate glycosaminoglycan, polyglytamate, polyaspartate, carboxymethyl-cellulose, dextran and etc (col. 11, lines 12-19).

Additionally, the limitation, which "facilitates cellular lysis", as recited in the claim is in reference to the presence of an anionic surfactant or detergent. Bloch et al teach this limitation as Bloch et al teach the presence of SDS on the membrane (Example 5).

Likewise, the limitation "which facilitates cellular lysis" does not distinguish over the prior art because it would have been expected to one of ordinary skill in the art that an anionic surfactant or detergent is capable of facilitating cellular lysis. MPEP 716.02 states, "Absence of property which a claimed invention would have been expected to possess based on the teachings of the prior art is evidence of unobviousness. *Ex parte Mead Johnson & Co.* 227 USPQ 78 (Bd. Pat. App. & Inter. 1985).

In response to Applicant's arguments concerning the different intended use of Bloch's reagents versus the instant invention, MPEP 2112.01 states that "where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established". *In re Best* 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). In this case, both the prior art and instant invention teach wherein the integrity maintenance means is a plastic bag which are identical products. Applicant's arguments are not persuasive and accordingly, the rejection is maintained.

New Ground(s) of Rejection

THE NEW GROUND(S) OF REJECTIONS ARE NECESSITATED BY APPLICANT'S AMENDMENT OF THE CLAIMS:

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Burgoyne (citation made of record in prior Office action).

Regarding claim 16, Burgoyne teaches a blood card (sheet or paper) comprising a dry solid matrix, wherein said matrix is a chemically modified cellulose, wherein the solid matrix further comprises a chemical coating functionally associated with the solid matrix, the chemical coating comprising a weak base, a chelating agent and an anionic surfactant or detergent which facilitates cellular lysis, an integrity maintenance means and indicator means, said card further comprising blood (col. 2, lines col. 47-64; col. 3, lines 1-6; col. 5, line 8-15 and Example 2). Therefore, Burgoyne meets the limitation of claim 16.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 1637

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 4-8, 12-17 and 37-46 are rejected under 35 U.S.C. 103(a) as being anticipated by Burgoyne (US 5,496,562, March 1996) in view of Ahern (The Scientist, vol. 20, pages 105, 1995). Regarding claims 4, 5, and 12, Burgoyne teaches a dry substrate consisting of a solid matrix comprises a cellulose-based paper (nitrocellulose) (col. 2, lines 21-25); a coating functionally associated with the solid matrix and wherein the coating comprises an anionic surfactant or detergent (col. 2, lines 59-64) and an indicator, which is maintained on the solid matrix, wherein the indicator is a color indicator (ink stamp or pencil marking) (col. 5, lines 8-15). Burgoyne does not teach wherein the dry substrate is packaged in the form of a kit.

In a scientific article, Ahern teaches the advantages of a kit and provides motivation for combining reagents in the form of a kit. Ahern teaches that a kit provides convenience, time management and ease of practicing to the investigator (page 23, second-fourth paragraphs). Therefore, in view of the teaching of Ahern, one of ordinary

Art Unit: 1637

skill in the art at the time of the claimed invention would have been motivated to have provided the dry solid substrate as taught by Burgoyne et al in the form of a kit for the obvious benefits of convenience, time management and ease of practicing to the investigator as suggested by Ahern.

Regarding claim 6, Burgoyne teaches wherein said substrate is a sheet (filter) or card (col. 2, lines 21-23 and col. 4, lines 61-65).

Regarding claim 7, Burgoyne teaches wherein the substrate further includes an integrity maintenance means (col. 3, lines 1-6).

Regarding claim 8, Burgoyne teaches wherein said substrate is a sheet (filter) and said integrity maintenance means is a plastic encasing (col. 3, lines 1-6).

Regarding claim 13, Burgoyne teaches the kit of claim 12, wherein the coated matrix is in a shape from the group consisting essentially of a sheet (col. 2, lines 24-25).

Regarding claim 14, Burgoyne teaches the kit of claim 12, wherein said coated matrix is in a shape selected from the group consisting essentially of a plastic bag (col. 5, line 52).

Regarding claims 37 and 41, Burgoyne teaches the kit of claims 4 and 12, wherein the anionic surfactant or detergent is SDS (col. 3, lines 24-25).

Regarding claims 38 and 42, Burgoyne teaches the kit of claims 12 and 37, wherein the weak base comprises a Tris and the chelating agent comprises EDTA (Example 1).

Art Unit: 1637

Regarding claims 39 and 43, Burgoyne teaches the kit of claims 4 and 12, wherein the anionic surfactant or SDS at a concentration of from about 5% (col. 4, line 37).

Regarding claims 40 and 44, Burgoyne teaches the kit of claims 4 and 12, wherein the coating further comprises a free radical trap (uric acid or a urate salt (col. 3, line 26 and 36-45).

Regarding claim 45, Burgoyne teaches the kit of claim 12, wherein the indicator means is a color indicator (col. 5, lines 8-15).

Regarding claim 46, Burgoyne teaches a kit comprising a dry solid matrix, wherein said matrix is a chemically modified cellulose, wherein the solid matrix further comprises a chemical coating functionally associated with the solid matrix, the chemical coating comprising a weak base, a chelating agent and an anionic surfactant or detergent which facilitates cellular lysis, an integrity maintenance means and indicator means (col. 2, lines col. 47-64; col. 3, lines 1-6; col. 5, line 8-15 and Example 2).

Claim Rejections - 35 USC § 103

11. Claims 47-52 are rejected under 35 USC 1103(a) as being unpatentable over Burgoyne in view of Ahern as discussed above and further in view of Bloch et al (applied above) and Anderson (5,89154, December 1996)

Regarding claims 47 and 52, Burgoyne in view of Ahern teaches a kit comprising a dry substrate comprising a solid matrix comprising chemically modified cellulose, the solid matrix being coated with a chemical coating functionally associated with the solid

Art Unit: 1637

matrix, the chemical coating comprising a weak base; a chelating agent; and an anionic surfactant or detergent and an indicator means.

Burgoyne does not teach wherein the indicator means comprises a polyethyleneimine conjugate or an ELISA.

Bloch et al teach a kit and dry solid medium similar to that disclosed in Burgoyne et al. Bloch et al further teach wherein the dry substrate comprising a solid matrix, wherein said solid matrix is nitrocellulose (col. 17, lines 52-64) and wherein the dry substrate comprises an indicator comprising an enzyme linked immunosorbant assay (col. 12, lines 28-47; and col. 17). In a general teaching, Anderson teaches the advantages of using ELISA. Anderson teaches that ELISA has the advantage in that they can be conducted using inexpensive equipment and with a myriad of different enzymes, such that a large number of detection strategies can be used to quantitate the assay (col. 14, lines 27-38). Therefore, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have included ELISA in the kit of Burgoyne in view of Ahern in view of Bloch based on the advantages taught by Anderson that ELISA can be conducted using inexpensive equipment and with a myriad of different enzymes, such that a large number of detection strategies can be used to quantitate the assay.

Regarding claim 48, Burgoyne teaches wherein the anionic surfactant or detergent is SDS (col. 3, lines 24-25).

Regarding claim 49, Burgoyne teaches wherein the weak base comprises a Tris and the chelating agent comprises EDTA (Example 1).

• Art Unit: 1637

Regarding claim 50, Burgoyne teaches wherein the anionic surfactant or SDS at a concentration of from about 5% (col. 4, line 37).

Regarding claim 51, Burgoyne teaches wherein the coating further comprises a free radical trap (uric acid or a urate salt (col. 3, line 26 and 36-45).

Conclusion

12. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

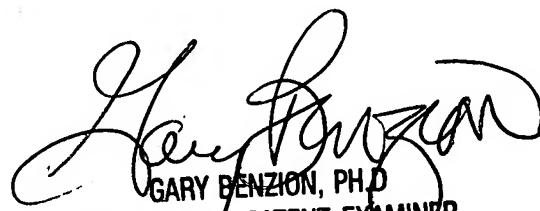
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

Art Unit: 1637

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cynthia B. Wilder, Ph.D.
Patent Examiner
Art Unit 1637


GARY BENZION, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600